## REMARKS

Claims 1, 3, 10-12, 17-20, 23-27, 34-38, 42-44, 47, 49-52, 54-56, 58 and 59 are pending. Claims 1, 26, 49, 50, 51, 52 and 56 have been cancelled without prejudice. New claims 60-62 have been added. Claims 3, 10, 12, 17-19, 23-24, and 54 have been amended to recite dependency from new independent claim 60 and claims 27, 34, 36-37, 42-44, 49, 51, 54-55, and 58-59 have been amended to recite dependency from new independent claim 62. Support for new claim 60 may be found in the specification as filed, *inter alia* at page 17, lines 6-8 and page 17, line 20 through page 19, line 1. Support for new claim 61 may be found in the specification as filed, *inter alia* at page 5, lines 3-10; page 17, lines 6-9; and page 17, line 20 through page 18, line 16. Support for new claim 62 may be found in the specification as filed, *inter alia* at page 6, lines 5-15; page 5, lines 3-10; page 17, lines 6-8 and page 17, line 20 through page 19, line 1. No new matter has been added. Applicants respectfully request entry of this amendment. Upon entry of the amendment claims 3, 10-12, 17-20, 23-25, 27, 34-38, 42-44, 47, 54-55, 58-62 will be pending.

**Claim of Priority to U.S. 09/204,254, now U.S. Patent No. 6,369,039**

The Examiner previously entered Applicant's claim to the benefit of the prior-filed copending nonprovisional application U.S. Ser. No. 09/204,254, filed December 3, 1998 now U.S. Patent No. 6,369,039 B1 ("'039").

However, the Examiner maintains the assertion that applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 because the claims are allegedly unsupported under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description as set forth in the previous Office Action mailed 6/4/03.

Applicant respectfully traverses and maintains that the '039 specification provides adequate support for the presently pending claims by explicitly guiding one of skill to *combine* a therapeutic agent and vector, as claimed in new independent claims 60 and 62 and claims dependent thereon. (Emphasis added)

The original description of the '039 patent provides a specific written description for the particular combination of a therapeutic agent and a vector encoding a polypeptide or protein selected from the above-recited group, as claimed. (See Col. 4, lines 64-67; Col. 5, lines 1-44; and Col. 5, line 62 through Col. 6, line 7). One of skill is clearly guided by the original '039 specification to combine a therapeutic agent and a vector by the explicit teaching at Col. 5, lines 62-65 of "the **polypeptides or proteins that can be incorporated into the polymer coating**

**130, or whose DNA can be incorporated**, include without limitation, angiogenic factors..." ... **"and combinations thereof" (See Col. 6, lines 7)**. Therefore, the '039 specification specifically lists the claimed therapeutic agents as well as polynucleotides encoding such therapeutic agents as being incorporated into the polymer coating and further clearly provides for combinations of such polypeptides/proteins **and** DNA with the ending phrase "and combinations thereof", indicating that combinations of therapeutic agents (polypeptides/proteins) and vectors containing DNA encoding polypeptides/proteins may be combined in the coating.

"[[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon '***reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter.***'" *Vas-Cath, Inc. v. Mahurkar* 935 F.2d 1555, 1563 (Fed. Cir. 1991) citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d1570, 1575, (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed.Cir. 1983)) (citations omitted) (Emphases added)

Claims to subject matter disclosed in the specification are not new matter. *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1539 (Fed. Cir. 1997) (finding that although the specification only discussed the claimed wrapping rate [of covering] with reference to a figure showing a one strand core, the specification disclosed a two strand core with a two strand covering.). The Court found that the accused infringer failed to show that the specification as a whole would have failed to convey to one of skilled in the art the use of the claimed wrapping rate with a two strand core, i.e., the claimed combination of elements which was not disclosed together.

In contrast, the '039 specification explicitly teaches that a combination of the claimed elements may be made. Therefore, the '039 specification fully supports a combination of therapeutic agents and vectors comprising polynucleotides encoding a polypeptide or protein selected from the above-recited group, as claimed. Accordingly, the written description requirement has been complied with and the presently pending claims should be entitled to the earlier filing date under 35 U.S.C. § 120. Applicant respectfully requests that such priority be afforded the benefit of the '039 filing date.

**Rejection of Claims 1, 3, 10-12, 17-20, 22-27, 30, 34-38, 42-44, 47, 49-52, 54-56, 58, 59 under 35 U.S.C. § 112, First Paragraph - Written Description**

The Examiner has maintained the rejection of claims 1, 3, 10-12, 17-20, 22-27, 30, 34-38, 42-44, 47, 49-52, 54-56, 58, 59 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey

to one of ordinary skill in the art that the inventor had possession of the claimed invention at the time the application was filed.

The Examiner states that the amendment of claims 1 and 26 in the response pursuant to 37 C.F.R. § 1.111 filed March 17, 2003 introduced new matter into the subject application.

The Examiner contends that the original specification does not disclose a medical device comprising a biocompatible structure carrying a genetic material comprising a first therapeutic agent comprising a vector containing a first polynucleotide wherein the first polynucleotide encodes an angiogenic agent; and a second therapeutic agent comprising a non-genetic therapeutic agent, wherein the non-genetic therapeutic agent is an angiogenic agent.

The Examiner continues to assert that "nothing in the specification that would lead one to the **particular combination** set forth in the amended claims." (Final Office Action mailed February 19, 2004, page 4, lines 1-12). (Applicant's emphasis added)

Claims 1 and 26 have been cancelled without prejudice. New claims 60-62 have been added.

Applicant respectfully traverses and maintains that the original specification specifically provides a teaching of a combination of a therapeutic agent selected from the above-recited groups in claims 60-62 and a vector containing a polynucleotide wherein the polynucleotide encodes a protein or polypeptide selected from the groups recited in claims 60 and 62.

The Examiner's attention is respectfully directed to page 17, lines 6-9 of the specification as originally filed, which states:

> The **first therapeutic agent of this invention comprises genetic materials** whereas the **second therapeutic agent of the invention may comprise** either genetic or **non-genetic materials**. The non-genetic material comprises any molecule or compound that induces a beneficial biological or medical reaction in vitro, or in vivo.

Further page 17, line 20 through page 18, line 16 of the originally filed subject specification provide examples of therapeutic agents and products encoded by the polynucleotides contained in the vector, as presently claimed. (*See* page 17, line 20 and page 16, line 21-22)

Therefore, *one of skill in the art* would be specifically guided by the subject specification to combine a therapeutic agent and a vector containing a polynucleotide wherein the polynucleotide encodes a protein or polypeptide selected from the group, as presently claimed in claims 60 and 62 and claims dependent thereon. Accordingly, the new claims do not add new matter into the subject application. Applicant respectfully requests reconsideration and

withdrawal of this rejection.

**Rejection of claims 50, 52, and 56 under 35 U.S.C. § 112, Second Paragraph**

The Examiner has maintained the rejection of claim 50 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. The Examiner opines that the term "small molecule" is a relative term and that one of ordinary skill in the art would not reasonably be apprised of the scope of the invention.

Without conceding the correctness of the Examiner's position, applicant has cancelled without prejudice claim 50 to expedite prosecution of the subject application.

The Examiner has maintained the rejection of claims 52 and 56 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite, as the term "site-specific" is not defined and that one of ordinary skill in the art would not reasonably be apprised of the scope of the invention.

Without conceding the correctness of the Examiner's position, applicant has cancelled without prejudice claims 52 and 56 expedite prosecution of the subject application. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, second paragraph is respectfully requested.

## CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Respectfully submitted,

KENYON & KENYON

April 12, 2004
Date

Elizabeth M. Wieckowski

Elizabeth M. Wieckowski
Reg. No. 42,226
KENYON & KENYON
One Broadway
New York, New York 10004
(212) 425-7000 (telephone)
(212) 425-5288 (facsimile)